



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,910	01/12/2006	Jonathan Alexander Terrett	2543-1-040PCT/US	1458
23565	7590	12/16/2010		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER HOLLERAN, ANNE L	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 12/16/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/524,910

**Applicant(s)**

TERRETT, JONATHAN  
ALEXANDER

**Examiner**

ANNE L. HOLLERAN

**Art Unit**

1643

***—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —***

THE REPLY FILED 17 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: \_\_\_\_\_  
Claim(s) withdrawn from consideration: \_\_\_\_\_

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because: Applicants state the Mack allegedly teaches methods for diagnosing ovarian cancer by detecting the expression of gene sequences provided in Tables 1-20, PTK7 being one of those hundreds of gene sequences provided in Tables 1-20. Applicants state that Gish allegedly teaches methods for diagnosing prostate cancer by determining the expression of a gene sequence provided in Tables 1-16, PTK7 being one of those hundreds of gene sequences provided in Tables 1-16. Applicants discuss the legal standard for applying a reference to be prior art under 35 USC 102; and state that a reference must enable its alleged teachings by teaching how to make the invention. Applicants state that Federal Circuit appears to require the prior art to enable practicing the claimed methods and refers to *Impax v. Aventis Pharmaceuticals* (Fed. Cir. 2008), which is a case in which it was agreed that a prior art reference was not enabling because the reference patent disclosed a formula encompassing hundreds or thousands of compounds for the treatment of several diseases. The court concluded that excessive experimentation would have been required to use one compound, riluzole, to treat one condition, ALS. Applicants also cite *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1335 (Fed. Cir. 2008) and *Minn. Mining & Mfg. Co. v. Chemque, Inc.* (3M), 303 F.3d 1294, 1301 (Fed. Cir. 2002) and *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) with respect to "undue experimentation". Applicants conclude that neither Mack nor Gish teach one or ordinary skill in the art how to make the presently claimed invention, i.e., how to diagnose, screen for or make a prognosis for a breast, pancreatic, lung, bladder or kidney cancer by detecting a PTK7 polypeptide comprising the amino acid sequence of SEQ ID NO: 1 in tissue obtained from a subject without undue experimentation, because neither Mack nor Gish indicate that a PTK7 polypeptide from among their tables of hundreds of genes might be useful for diagnosing, screening for or making a prognosis for any cancer, much less a breast, pancreatic, lung, bladder or kidney cancer.

Applicants' arguments have been carefully considered, but fail to persuade. In the previous Office action mailed 8/12/2010 the examiner stated that the fact that Mack teaches detecting and/or quantifying SEQ ID NO: 1 in ovarian tissue does not place Mack outside the scope of the claims because Mack teaches detection and/or quantification of SEQ ID NO: 1 in tissues such as lung, kidney or bone (see page 3). Previously, the examiner stated that the instant claims are interpreted as claims that comprise the step of detecting or quantifying a PTK7 polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO: 1 in a biological sample selected from breast, pancreatic, lung, bladder, kidney or bone tissue obtained from a subject. Mack and Gish both teach methods comprising this step. Applicants are defining the claims to include the preamble of the instant claims as if the preamble limited the scope of the claims, and from this position are comparing the instant claims with the situation found in *Impax v. Aventis Pharmaceuticals* (Fed. Cir. 2008). Because the claims at issue in *Impax* are claims drawn to methods of treatment for a specific disease, the methods require treating a specific patient population (those having that specific disease). Thus, where the alleged prior art was not found to be enabling for the *Impax* case, because the the alleged prior art did not teach the specific drug for the treatment of a specific disease, such is not the case for the instant claims. In the instant application the claims are drawn to the detection and/or quantification of PTK7 in specific tissues. These specific tissues are taught by Mack (lung, kidney or bone), or Gish (breast or lung tissue), and the detection of PTK7 is taught by Mack or Gish. Therefore, the prior art methods are enabled because one of skill in the art is taught how to perform this step and in what tissue.